Baxter

NON-CBI VERSION VIA U.S. MAIL
Ethylene Oxide Commercial Sterilization Section 114 ICR Response
U.S. EPA Office of Air Quality Planning and Standards
Sector Policies and Programs Division, Fuels and Incineration Group
Mail Code E143-05
109 T.W. Alexander Drive
Research Triangle Park, NC 27711

CBI VERSION VIA U.S. MAIL
U.S. EPA Office of Air Quality Planning and Standards
U.S. EPA Mailroom (C404-02)
Attn: Ms. Tiffany Purifoy, Document Control Officer (ESD #322)
109 T.W. Alexander Drive
Research Triangle Park, NC 27711

November 19, 2021

RE: EtO Commercial Sterilization Information Collection Request OMB Control No. 2060-0733

Ms. Purifoy:

Enclosed is Baxter's response to the Clean Air Act Section 114 Information Collection Request (ICR) issued by the United States Environmental Protection Agency (EPA) to the Mountain Home commercial sterilization facility owned and operated by Baxter Healthcare Corporation, a subsidiary of Baxter International Inc. (Baxter). Our response is provided electronically in Excel spreadsheet format on the enclosed media, as requested, and also it includes various attachments in response to the questions that sought the submission of certain documents.

We have prepared two different versions of our response on separate media to assist EPA in identifying and preventing the disclosure of Confidential Business Information (CBI). Please note the media is encrypted, and the password is "EPA114ICR." This cover letter is enclosed with both versions and itself does not contain CBI, but the version of Baxter's response provided on the media marked as "CBI" contains trade secret and other highly sensitive proprietary information that is not publicly available and that could be used by the company's competitors to identify its operating procedures, financial status, and selection of equipment and technologies, including proprietary processes and vendor arrangements. Baxter has taken reasonable measures to keep the information confidential and will continue to do so for the life of the Mountain Home facility because the public release of the information could cause substantial harm to Baxter's competitive position in the marketplace. As such, it is entitled to confidential treatment within the meaning of 40 CFR Part 2 and any other similar applicable law, and the information is submitted with the expectation that EPA will fully comply with the requirements of 40 CFR Part 2 prior to any release of the information, including EPA's responsibility to provide Baxter an opportunity to further substantiate its confidentiality claims prior to any final determination of confidentiality if needed.

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Baxter has made reasonable efforts to provide a complete response. The responses reflect information about the Mountain Home facility that was available as of the date the ICR was received. Please note that several changes to the air pollution control devices utilized at the facility are anticipated in the coming years to implement the terms of an agreement between Baxter and its authorized state permitting authority, the Arkansas Department of Environmental Quality (DEQ), to further reduce the potential air emissions from the facility. Because the plans for future changes to the facility remain somewhat in flux and subject to applicable air permitting activities that remain underway, Baxter's responses only reflect the current status of the facility. However, more information on the changes to come at the facility may be obtained via review of the agreement with DEQ, which is available on DEQ's website.

Baxter's responses to the ICR are also provided subject to certain objections. First, Baxter objects to EPA's request for information to the extent it seeks information not reasonably related to the purpose of the ICR as authorized by the Clean Air Act; i.e., the review of the National Emission Standards for Hazardous Air Pollutants (NESHAP) for Sterilization Facilities, 40 C.F.R. part 63, subpart O, which applies to stationary sources where ethylene oxide (EtO) is used in the sterilization or fumigation of materials. Accordingly, Baxter has not responded to the request for information on non-EtO sterilization methods, information on facilities that are not subject to the standard under review, or data that does not represent accurate facility information. Second, Baxter objects to portions of EPA's request that were overly burdensome within the time allowed. Despite the comprehensive and highly extensive nature of the ICR, EPA allowed only 67 days between the date of the ICR and the deadline for a response. Baxter requested an extension, but EPA did not grant that request. As a result, Baxter's response reflects the information that could reasonably be collected and verified for accuracy within the time allowed. Third, Baxter objects to the request for information that the facility does not have in its possession or that the facility is not required by law to maintain. Accordingly, some of the information requested could not be provided or is provided subject to certain qualifications identified in the response. Finally, to the extent EPA's request sought any information protected by the attorney client communication privilege or attorney work product doctrine, Baxter objects to any request for such information. Thus, Baxter's response to the ICR does not contain any privileged or otherwise protected communications, information, or documents.

We appreciate the opportunity to provide information to EPA to assist in its review of Subpart O. If you have any questions regarding this response, please contact me at your convenience.

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